REMARKS

Applicants seek to amend Claims 1, 4, 6 and 19, cancel Claims 3 and 37 and add new Claims 59 to 60 at this time to put the application in better form for appeal. After entry of this amendment, Claims 1, 4, 6, 19-21, 31, 36, 38, 39, 52, 53, 55 and 59 to 60 will be pending.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 1, 3, 4, 6, 19-21, 31, 36-39, 52, 53, and 55 as being indefinite due to the reference to a "blood component". The rejection is avoided by proposed amendments to independent claims 1 and 19 to replace "blood component" with "serum albumin." Support for this amendment exists on page 10, paragraph 1 of the specification as filed. The relevant text is reproduced here:

> "Mobile blood components include serum albumin, transferrin, ferritin, and immunoglobulins such s IgM and IgG."

In light of these amendments, pending claims 1, 4, 6, 19-21, 31, 36, 38, 39, 52, 53, and 55 all now refer to serum albumin instead of a "blood component". Applicants respectfully assert that the pending claims therefore meet the requirements of 35 U.S.C. § 112, Second Paragraph and request withdrawal of the rejection and reconsideration of these claims.

Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1, 3, 4, 6, 19-21, 31, 36-39, 52, 53, and 55 as being "unpatentable over Bolognesi et al (1996) in view of Tolman et al. (1993) and further in view of Patrick, et al. (1987)."

The Examiner is respectfully reminded that in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references must teach or suggest all claim limitations. The amended claims simply do not meet these criteria.

Claims 1 and 19 are now limited to a peptide with a maleimide group which is covalently bonded to cysteine 34 of serum albumin, where the ratio of peptide to serum albumin is 1:1. Support for this amendment is found on page 27, line 9 and 17 of the specification as filed. The relevant sections are reproduced here:

> "...peptide-malemide-albumin conjugates will tend to comprise approximately a 1:1 molar ratio of peptide to albumin."

> "The single free thiol group of albumin, highly conserved among species, is located at amino acid residue 34 (Cys^{34})."

None of the references cited by the Examiner, alone or together, disclose or suggest the covalent bonding of a peptide to cysteine 34 of serum albumin in a 1:1 ratio of peptide to serum albumin. Instead, the references disclose conventional conjugation methods that produce conjugates with several molecules of active agent coupled to each molecule of carrier. As such, the conventional conjugation methods cited by the Examiner produce a heterogeneous pool of conjugates at various ratios of molecule to carrier. In contrast, in the presently claimed invention, the conjugate is a 1:1 ratio of molecule (peptide) to carrier (serum albumin) where the peptide is specifically bonded to cysteine 34 of serum albumin.

Bolognesi, et al. disclose HIV derived peptide sequences, and Tolman, et al. disclose the preparation of a vaccine by the conjugation of peptides to a bacterial carrier protein, OMPC. Patrick et al. disclose a vaccine that can be made with BSA (Bovine Serum Albumin) as a carrier. Patrick et al. disclose "using standard techniques with a bifunctional conjugating agent such as carbodiimide, glutaraldehyde or bis-diazotized benzidine." (see col. 16, lines 10-15 of Patrick, et al.). These bifunctional conjugating agents react with amines, not with thiol groups. The bifunctional agents of Patrick, et al. provide conjugates where the peptides are attached at non-specific sites on the BSA.

The differences between the claimed invention and the techniques of the prior art including Patrick, et al. are outlined in the present specification as filed on page 28, lines 3-6, which provides:

"Another advantage of peptide-maleimide-albumin conjugates is the reproducibility associated with the 1:1 loading of peptide to albumin specifically at Cys34. Other techniques, such as glutaraldehyde, DCC, EDC and other chemical activations of, e.g., free amines, lack this selectivity."

Patrick, et al. disclose the creation of a vaccine by conjugation of a peptide to an immunogenic carrier molecule. Column 16, line 26 of Patrick et all provides "[t]he result of this conjugation reaction will be a mixture of synthetic proteins of the invention, each involving a different number of molecules of synthetic peptide conjugated per molecule of carrier protein." In contrast the claims of the present invention are directed to peptides that are specifically conjugated via a maleimide group to cysteine 34 of serum albumin, resulting in a 1:1 ratio of peptide to serum albumin.

There is no suggestion or motivation to modify the references or to combine reference teachings to produce the claimed inventions as none of the references, either alone or together, teach or suggest conjugation of a peptide via a maleimide group to cysteine 34 of serum albumin, resulting in a 1:1 ratio of peptide to serum albumin. The prior art references do not teach or suggest all claim limitations. As such, there is not reasonable expectation of success.

Applicants submit that the Examiner has not set forth a proper *prima facie* case of obviousness and respectfully request withdrawal of the present rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and

authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 500862001520. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By Michael R Ward

Michael R. Ward
Registration No.: 38,651
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105
(415) 268-6237